REMARKS

Claims 1-13, 15-31, and 33-40 are currently pending in the application. Claims 1, 4, 13, 15, 18-31, 33, 35, 37, 39, and 40 are in independent form.

The Office Action states that an Abstract was not included on a separate sheet as is required. Accordingly, an Abstract has been included herewith on a separate sheet of paper.

The Office Action states that the incorporation of essential material in the specification by reference to a foreign application, patent, or publication is improper. The Office Action cites specific reference to where such incorporation by reference has been made. In order to further prosecution, the specification has been amended without adding any new matter to overcome the present objection. Reconsideration of the objection is respectfully requested.

Claims 27-29 and 39 stand rejected as being directed to products of nature that have not been isolated and purified, and as such, are non-statutory subject matter. The claims have been amended to recite that the products are isolated and purified, and as such, are statutory subject matter. Reconsideration of the rejection is respectfully requested.

Claim 39 stands rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Office Action states that a genus of peptides that comprise SEQ ID NO. 3 are claimed but only a single species of protein has been described. However, a variant is disclosed on page 27, lines 20-27. Various methods of creating a variant and what would be included in that variant are disclosed. Additionally, at page 20, line 20 through page 21, line 7, there is disclosed variant forms of the ebaf protein that are isolated from the samples and methods of distinguishing between these variants. There is disclosed in the specification multiple variants; any additional variants are

within the common purview of those skilled in the art. Since those skilled in the art are able to form such variants based on the disclosure of the presently pending application, reconsideration of the rejection is respectfully requested.

Claims 1-26, 28-38, and 40 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Office Action states that the claimed invention is directed to methods of determining, detection devices that comprise, contraceptives that comprise, and diagnostic tools that comprise ebaf nucleotide splice variants and reagents that are nucleotide molecules that will detect these variants. The Office Action states that the specification only discloses the nucleotide sequence for ebaf. However, a variant is disclosed on page 27, lines 20-27. In this specific section of the specification, there is disclosed various methods of creating a variant and what would be included in that variant. Additionally, at page 20, line 20 through page 21, line 7, there is disclosed variant forms of the ebaf protein that are isolated from the samples and methods of distinguishing between these variants. There is disclosed in the specification multiple variants; any additional variants are within the common purview of those skilled in the art. Since those skilled in the art are able to form such variants based on the disclosure of the presently pending application, reconsideration of the rejection is respectfully requested.

Claims 1-26, 27, 28, and 40 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the utilization of serum, endometrial samples, and antisera that specifically bind to ebaf for determining the presence or absence of ebaf, does not reasonably provide enablement for the determination of ebaf or variants thereof in any sample of tissue, or body fluids such as brain tissue, saliva, and fecal samples for the determination of fertility or infertility. In order to further prosecution, the claims have been amended to be limited to endometrial fluid, serum, urine, and saliva as is specifically stated in the specification on page 26, lines 1-3, without prejudice.

Further, the Office Action states that the utilization of antibodies to ebaf nucleotides has not been described in such a way that Applicant conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, the inventor was in possession of the invention. More specifically, the Office Action states that a person skilled in the art would be required to conduct undue experimentation to utilize any tissue or bodily fluid to determine the presence of ebaf using an antisera or mRNA of any sequence that may be cross-reactive and/or non-specific for ebaf. However, the utilization of antibodies is clearly disclosed on pages 24, line 29 through page 25, line 11; page 29, line 18 through page 31, line 14; page 41, line 1 through page 42, line 6; and page 71, line 8 through page 72, line 15. Throughout the specification and at the specific locations disclosed above, there is specifically disclosed how to formulate antibodies to the specific sequences. There is, therefore, sufficient support in the specification for the claims claiming antibodies. Additionally, it is well within the knowledge of one skilled in the art to utilize the specific bodily fluid disclosed and claimed herein to detect the presence of ebaf using well-known methods specifically disclosed within the specification at the locations disclosed above. Accordingly, reconsideration of the rejection is respectfully requested.

Claims 1-40 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention.

The Office Action states that claims 1-3, 18-26, and 30 are directed to various methods that recite steps in the passive voice. The claims have been amended to recite the steps in active voice and reconsideration of the rejection is respectfully requested.

The Office Action states that claims 1-3 recite the phrase "by screening," but a sample has not been provided and the screening results have not been compared with any reference sample or negative control. In order to further prosecution, the claims have been amended to more specifically recite the sample without prejudice. The Office Action questions what is intended by the terms "ebaf"

and "ebaf variant." As stated previously, there is sufficient disclosure in the specification for the methods and terms as presently claimed. Reconsideration of the rejection is respectfully requested.

The Office Action states that claim 1 recites the term "ebaf" and the utilization of abbreviations in the claims is only permitted upon definition of the term at the first appearance in the claims. In order to further prosecution, the claims have been amended to clearly define what is intended by the term "ebaf" in claim 1. Reconsideration of the rejection is respectfully requested.

Claim 2, according to the Office Action, recites "ebaf" and defines the screening step to further comprise either a Northern blot or a Western blot. Claim 2 has been amended in order to further prosecution to clarify what is being screened. Reconsideration of the rejection is respectfully requested.

Claim 3 recites the phrase, "further includes immunohistochemical staining," and the Office Action questions what is inclusive in the immunohistochemical staining claimed. The specification discloses the immunohistochemical staining that is being conducted and this disclosure provides sufficient clarity to those of skill in the art for performing the staining. Further, the phrase immunohistochemical staining "is acknowledged by those skilled in the art to indicate a certain methodology. This methodology is known to those skilled in the art and can be conducted pursuant to the disclosure in the specification. Accordingly, there is sufficient disclosure in the specification for the phrase and reconsideration of the rejection is respectfully requested.

Claims 4, 5, and 6 stand rejected as being directed to screening means without including any further structure. However, the screening means can be defined broadly as long as the definition is clearly described in the specification. The specification clearly establishes that the screening means can be a Northern blot analysis, a Southern blot analysis, or a Western blot analysis. These methods include all of the chemicals required for performing the methods. Since the specification clearly establishes what is inclusive of the screening means, the

claims as written provide sufficient clarity to those skilled in the art and reconsideration of the rejection is respectfully requested.

The Office Action states that claim 7 recites the phrase, "screening means is an immunohistochemical stain." The Office Action states that there is not sufficient disclosure in the specification to provide enablement for the phrase and clarification of what the tool is, is requested. However, the immunohistochemical staining method is disclosed in the specification, and since applicant can be his own lexicographer, it is respectfully submitted that there is sufficient disclosure in the specification for the verbiage used in the claims. Reconsideration of the rejection is respectfully requested.

Claims 8 and 9 stand rejected as being confusing with regard to whether an mRNA or protein is being claimed. The claims have been amended to more specifically recite what is being claimed, and reconsideration of the rejection is respectfully requested.

Claims 10-12 recite "wherein" clauses that define specific diseases that are being diagnosed. These claims have been amended to more specifically define what is being claimed, and what is used to diagnose the diseases. Specifically, the claims have been amended to recite that the diagnostic tool broadly claimed can be used in diagnosing multiple diseases. Therefore, there is sufficient disclosure in the specification and sufficient clarity with regard to the language of the claims as presently pending. Reconsideration of the rejection is respectfully requested.

Claims 13 and 14 stand rejected as being directed both to a composition and a device, which are in fact the same thing. In order to further prosecution, the device claim (claim 14) has been cancelled and reconsideration of the rejection is respectfully requested.

Claim 15 stands rejected as being directed to, "screening means for screening a sample for the presence of ebaf," specifically for timing conception. The Office Action requests the structure of the means. However, the structure is fully disclosed in the specification. Screening means is a broad term used to cover

all screens that can be used to detect the presence of ebaf. As stated previously, this can include any number of blot analyses or a PCR analysis. Accordingly, since there is sufficient disclosure in the specification for the broad use of the phrase, "screening means," reconsideration of the rejection is respectfully requested.

Claim 16, according to the Office Action, does not clearly discern what is being claimed. Claim 16 has been amended to claim a protein encoded by ebaf. Reconsideration of the rejection is respectfully requested.

Claim 18 recites the phrase, "by down-regulating the expression of ebaf," but the Office Action states that it does not disclose what is required for this to occur. The claim does not specifically describe how the down-regulation occurs because there is broad disclosure within the specification that enables any method of down-regulating the expression of ebaf to be within the scope of the pending claim. The down-regulation can occur by any method known to those skilled in the art and specifically disclosed within the specification. Accordingly, there is sufficient disclosure in the specification for the phrase and reconsideration of the rejection is respectfully requested.

Claim 19, according to the Office Action, is directed to a method for "determining endometrial receptivity." The Office Action questions of what the endometrium is receptive. As disclosed in the specification at page 26, line 28 through page 27, line 10, and encompassed within Example 4, the endometrial receptivity is for determining conception. In other words, the determination is whether the endometrium is receptive to implantation and subsequent pregnancy. This phrase is known to those skilled in the art and is clearly disclosed in the specification. Accordingly, reconsideration of the rejection is respectfully requested.

Claims 20-23, according to the Office Action, recite the method as claim 19, with a different "by determining" phrase. However, when read more specifically, claim 19 does not specifically claim how the down-regulation occurs because there is broad disclosure within the specification that enables any method of down-regulating the expression of ebaf to be within the scope of the pending claim. The down-regulation can occur by any method known to those skilled in the

art and specifically disclosed within the specification. Claims 20-23 more specifically claim the methodology used for determining the receptivity. In other words, these claims more specifically define the screening tool that is used to determine whether receptivity is possible at that time. Reconsideration of the rejection is respectfully requested.

Claims 24-26 recite the phrase, "determining optimal treatment or treatment response." The Office Action questions what is included by optimal treatment, how the treatment is achieved, etc. Optimal treatment is disclosed in the specification as treatment that either enables the individual to become pregnant or prevents the person from becoming pregnant. In other words, enablement or prevention of pregnancy is determined based upon the desired result. If the treatment is contraceptive, then the optimal treatment and treatment response would be the lack of pregnancy. Alternatively, if the treatment is to induce or result in a pregnancy, then the response would be a modification of levels of ebaf in the person's system sufficient to induce pregnancy. This is clearly disclosed throughout the specification, and specifically in Example 4 and also on page 26, lines 28 through page 27, line 10. Based on these explicit teachings, reconsideration of the rejection is respectfully requested.

Claim 27 is directed to an antisera to ebaf. The Office Action questions to what the antisera is specific. This is disclosed on page 22, lines 22-31 and more specifically in the examples. The specification discloses the source of the antisera, methods of creating the antisera, and the benefits of the antisera. Accordingly, to what the antisera is directed is disclosed in the specification and reconsideration of the rejection is respectfully requested.

Claims 28 and 29 are directed to markers for receptivity and infertility, both being defined as being ebaf. The Office Action questions whether a molecule can be indicative of both extremes. On page 19, lines 1-12, there is disclosed how this is possible. More specifically, the markers for receptivity and infertility are based upon the quantity of ebaf that is present in the sample. In other words, one extreme quantity indicates infertility, another extreme quantity indicates receptivity.

Therefore, the same sequence can be both a marker for infertility and a marker for receptivity. Reconsideration of the rejection is respectfully requested.

Claim 30 recites the phrase "by modulating" and the Office Action requests clarification with regard to a substance that modulates the amount of ebaf produced. As disclosed throughout the examples and the specification, the compound is any product that is capable of modifying ebaf production. As ebaf is known to those skilled in the art, methods of modulating ebaf and compositions for modulating ebaf, are known to those skilled in the art. Reconsideration of the rejection is respectfully requested.

Claim 31 is directed to an immunohistology test. The reagents contained within that test are clearly known to those of skill in the art and are disclosed throughout the specification. Accordingly, the claim is sufficiently clear and reconsideration of the rejection is respectfully requested.

The Office Action states that claim 32 recites, "further includes antisera" and depends from claim 31. In order to further prosecution, claim 32 has been cancelled without prejudice, thereby rendering the present rejection moot. Reconsideration of the rejection is respectfully requested.

Claim 33 is directed to a kit for an immunoassay. The specificity with regard to the reagents needed for the kit is included on page 22, lines 20-31 and throughout the examples. Accordingly, reconsideration of the rejection is respectfully requested.

Claims 34 and 36 recite the phrase, "antisera and peptides as positive controls." This is disclosed on page 22, lines 22-31 and more specifically in the examples. The specification discloses the source of the antisera, methods of creating the antisera, and the benefits of the antisera. Accordingly, to what the antisera is directed is disclosed in the specification and reconsideration of the rejection is respectfully requested.

Claim 35 recites the phrase, "blotting test." The type of blotting test included is disclosed in the specification. However, the blotting test can be defined broadly as long as the definition is clearly described in the specification. The

specification clearly establishes that the blotting test can be a Northern blot analysis, a Southern blot analysis, or a Western blot analysis. These methods include all of the chemicals required for performing the methods. Since the specification clearly establishes what is inclusive of the blotting test, the claims as written provide sufficient clarity to those skilled in the art and reconsideration of the rejection is respectfully requested.

Claims 37 and 38 are directed to kits comprising "a PCR" and details regarding the PCR are respectfully requested. The reagents contained within that test are clearly known to those of skill in the art and are disclosed throughout the specification. Accordingly, the claim is sufficiently clear and reconsideration of the rejection is respectfully requested.

Claim 40 is directed to a device for the detection of at least one variant of ebaf. However, a variant is disclosed on page 27, lines 20-27. In this specific section of the specification, there is disclosed various methods of creating a variant and what would be included in that variant. Additionally, at page 20, line 20 through page 21, line 7, there is disclosed variant forms of the ebaf protein that are isolated from the samples and methods of distinguishing between these variants. There is disclosed in the specification multiple variants; any additional variants are within the common purview of those skilled in the art. Since those skilled in the art are able to form such variants based on the disclosure of the presently pending application, reconsideration of the rejection is respectfully requested.

Claims 1-5, 9-14, 18-19, 22-26, 28-29, 35, 37, and 39-40 stand rejected under 35 U.S.C. § 102(a) as being anticipated by the Kothapalli, et al. reference. Reconsideration of the rejection under 35 U.S.C. § 102(a), as anticipated by the Kothapalli, et al. reference, as applied to the claims, is respectfully requested. Anticipation has been always held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action states that the Kothapalli, et al. reference discloses a method of diagnosing endometrial irregularities by screening an endometrial sample of bodily fluid for the presence of ebaf. The Office Action states that the inventive entity of the Kothapalli, et al. reference is different from the inventive entity of the instant application. Attached hereto is a declaration which has been signed by the inventor indicating that while the authoritative entity of the Kothapalli, et al. reference is different, this is not indicative of a difference in inventive entity. The individuals involved with the publication were not in fact inventors. Thus, the Kothapalli, et al. reference is not prior art for the present application. Reconsideration of the rejection is respectfully requested.

Claims 4-12, 15-17, 20-21, 27-29, 31-38, and 40 stand rejected under 35 U.S.C. § 102(e) as being anticipated by the Tabibzadeh, et al. patent. Reconsideration of the rejection under 35 U.S.C. § 102(a), as anticipated by the Kothapalli, et al. reference, as applied to the claims, is respectfully requested. Anticipation has been always held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action states that the Tabibzadeh, et al. patent discloses kits, diagnostic tools, antisera to EBAF. However, there is no disclosure in the patent for the use of this in determining anything outside the scope of cancer. More specifically, there is no disclosure in the Tabibzadeh, et al. patent for the use of ebaf in detecting endometrial irregularity. The presently pending independent claims specifically claim detecting and treating endometrial irregularities. Specifically, some of the independent claims claim treating fertility and infertility. There is no suggestion or teaching in the Tabibzadeh, et al. patent of this

correlation to endometrial irregularity. Accordingly, since the Tabibzadeh, et al. patent neither discloses nor suggests the ebaf for use in detecting endometrial irregularities as disclosed in the presently pending independent claims, the claims are patentable over the Tabibzadeh, et al. patent and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

Amy E. ~~Rinaldo~~, Reg. No. 45,791
30500 Northwestern Highway
Suite 410
Farmington Hills, Michigan 48334
(248) 539-5050

Dated: November 13, 2002

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on November 13, 2002.

Connie Herty

Connie Herty

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

Page 31, line 20 through page 32, lines 1-5:

Transgenic and Knockout Methods: The present invention may provide for transgenic gene and polymorphic gene animal and cellular (cell lines) models as well as for knockout models wherein the gene associated with human female infertility is either inserted and/or the corresponding animal gene "knocked out."[.] These models can, for example, be used for the study of therapeutics for treating infertility. These models are constructed using standard methods known in the art and as set forth in United States Patents 5,487,992, 5,464,764, 5,387,742, 5,360,735, 5,347,075, 5,298,422, 5,288,846, 5,221,778, 5,175,385, 5,175,384, 5,175,383, 4,736,866 as well as Burke and Olson (1991); Capecchi (1989), Davies, et al. (1992), Dickinson et al. (1993), Duff and Lincoln (1995), Huxley et al. (1991), Jakobovits et al. (1993), Pearson and Choi (1993), Rothstein (1991), Schedl et al. (1993), Strauss et al. (1993). [Further, patent applications WO 94/23049, WO 93/14200, WO 94/06908, WO 94/28123 also provide information.]

Page 57, lines 5-26:

To determine whether the dysregulated immunoreactive ebaf was the correct immunoreactivity was examined in the endometria of patients with endometriosis. In some women, the endometriosis is associated with infertility whereas in others, its presence does not preclude pregnancy [30-31)]. As compared with the control fertile endometria, the ebaf protein bands were as abundant as those found during the late secretory and menstrual phase (Figure 9, compare with normal control shown in Figure 8). With the exception of one patient, however, this dysregulated expression of the ebaf protein species was more pronounced in infertile women with endometriosis as compared with women with endometriosis who became pregnant (Figure 9). The ebaf immunoreactivity

was then examined in the endometria of a 6 infertile women with endometriosis who underwent treatment for their infertility (Figure 10). Four patients, in whom treatment [lead] led to a decrease in the immunoreactive ebaf bands, subsequently became pregnant after treatment (Figure 10). On the other hand, two additional patients in whom the treatment was associated with an increase in the immunoreactive ebaf bands, did not become pregnant (Figure 10).

Page 58, lines 15 through Page 60, lines 1-5:

DISCUSSION

ebaf was identified as a member of the premenstrual/menstrual molecule repertoire in human endometrium [(7-8)]. By Northern blot analysis, the *ebaf* mRNA was abundant in the late secretory and menstrual endometria. Based on the amino acid component of the *ebaf*, the size of the precursor protein was estimated to be 41 kD. Consistent with this size, a 41 kD protein band which appeared as a doublet, when adequately resolved, was detected in the Western blot analysis of the endometrial proteins. The NIH-3T3 cells transfected with *ebaf*, the also expressed the 41 kD protein. Presence of a signal peptide suggested that *ebaf* may be a secreted protein. Three potential cleavage sites exist within the *ebaf* precursor leading to 32.3, 25.7 and 12 kD secreted proteins. The Western blot analysis of endometrium, endometrial fluid, and serum revealed protein bands of 31 and 25 kD. The relatively lower abundance of this protein accounts for the lack of its detection by the Western blot analysis. However, when immunoprecipitated, a ~12 kD protein was also detected in the endometrium. Similarly, the transfection of the NIH-3T3 cells with *ebaf* led to the secretion of a 32 and 25 kD as well as the ~12 kD protein. In addition to these bands, a 55 (55/60) kD protein band was detected by the Western blot analysis in the endometrium, endometrial fluid and serum. Since the immunoreactivity of the antibody with this band could be inhibited by pre-incubation with the peptide, it seems that this band may represent ebaf protein, which in view of its size, may be a post-translationally modified product. Some of the proteins detected in the

tissue lysates of endometrium may be secretory products that reside outside the cells and which ultimately enter the peripheral circulation. Consistent with this hypothesis, the ebaf protein could be detected in the endometrial fluid and sera. The immunohistochemical staining showed that some of the protein is detectable within the endometrial cells. The presence of the 41 kD precursor protein in the serum is unusual. However, the 41 kD was also secreted from the transfected cells indicating that it may be released to the outside of the cells. It is interesting to note that serpins that inhibit Furin and which lack the typical cleavable N-terminal signal sequence have been found to reside extra-cellularly. ebaf protein was found in the male sera indicating that sources other than uterus exist in the body that make *ebaf*. Using Northern blot hybridization, it was shown that the *ebaf* mRNA is expressed, at a low level, in the pancreas, rectum, ovary and testis. The mRNA of many cytokines is expressed at a low copy number, yet, this is sufficient for the translation of an adequate number of cytokine molecules active in the tissue micro environment. This is the basis for the detection of the ebaf protein by Western blot analysis in the endometrium during the proliferative phase of the menstrual cycle, in presence of a low level of *ebaf* mRNA. The 25 kD and not the 31 kD protein bands were detected in the male sera suggesting that only the 31 kD protein may be uterine specific. Thus, the amount of this protein species in the serum reflects the amount of the *ebaf* synthesized by the endometrium.

IN THE CLAIMS:

1. (Amended) A method of diagnosing endometrial irregularities[by] comprising the step of screening an endometrial sample [or bodily fluid] endometrial fluid, endometrial serum, urine, or saliva for the presence of the endometrial bleeding associated factor (*ebaf*), [or] *ebaf* splice variants, or the proteins encoded by *ebaf* that are differentially expressed compared to controls.

NM

4. (Amended) A diagnostic tool for determining the presence of endometrial irregularities comprising:

screening means for screening an endometrial sample, endometrial fluid, endometrial serum, urine, or saliva for the presence of *ebaf*.

5. (Amended) The diagnostic tool according to claim 4, wherein said screening means is a Northern blot [analysis] kit.

6. (Amended) The diagnostic tool according to claim 4, wherein said screening means is a Western blot [analysis] kit.

8. (Amended) The diagnostic tool according to claim 4, wherein the [*ebaf*] protein encoded by *ebaf* is detected.

9. (Amended) The diagnostic tool according to claim 4, wherein [the] said screening means detects mRNA encoding *ebaf* [is detected].

10. (Amended) The diagnostic tool according to claim 4, wherein the endometrial irregularity being screened is infertility.

11. (Amended) The diagnostic tool according to claim 4, wherein the endometrial irregularity being screened is endometriosis.

12. (Amended) The diagnostic tool according to claim 4, wherein the endometrial irregularity being screened is abnormal uterine bleeding.

Please cancel claim 14.

15. (Amended) A diagnostic kit for timing conception comprising screening means for screening an endometrial sample, endometrial fluid, endometrial serum, urine, or saliva for the presence of *ebaf*.

16. (Amended) The diagnostic kit according to claim 15, wherein the *ebaf* is a protein encoded by *ebaf*.

18. (Amended) A method of treating endometrial irregularities [by] comprising administering a compound for down-regulating the expression of *ebaf*.

19. (Amended) A method for determining endometrial receptivity level by determining the levels of *ebaf* by sampling endometrial tissue [and bodily fluids], endometrial fluid, endometrial serum, urine, or saliva.

20. (Amended) A method for determining endometrial receptivity level by determining the levels of *ebaf* in an endometrial sample, endometrial fluid, endometrial serum, urine, or saliva by immunoassay.

21. (Amended) A method for determining endometrial receptivity level by determining the levels of *ebaf* in an endometrial sample, endometrial fluid, endometrial serum, urine, or saliva by immunohistology.

22. (Amended) A method for determining endometrial receptivity level by determining the levels of *ebaf* in an endometrial sample, endometrial fluid, endometrial serum, urine, or saliva by PCR.

23. (Amended) A method for determining endometrial receptivity level by determining the levels of *ebaf* in an endometrial sample, endometrial fluid, endometrial serum, urine, or saliva by northern, western, or southern blot.

24. (Amended) A method of diagnosis and prognosis of infertility by determining optimal treatment or treatment response by determining *ebaf* levels in an endometrial sample, endometrial fluid, endometrial serum, urine, or saliva.

25. (Amended) A method of diagnosis and prognosis of endometriosis by determining optimal treatment or treatment response by determining *ebaf* levels in an endometrial sample, endometrial fluid, endometrial serum, urine, or saliva.

26. (Amended) A method of diagnosis and prognosis of menometrorrahgia by determining optimal treatment or treatment response by determining *ebaf* levels in an endometrial sample, endometrial fluid, endometrial serum, urine, or saliva.

27. (Amended) An isolated and purified antisera directed to *ebaf*.

28. (Amended) An isolated and purified marker present in bodily fluids in an endometrial sample, endometrial fluid, endometrial serum, urine, or saliva for determining endometrial receptivity comprising *ebaf*.

29. (Amended) An isolated and purified marker in bodily fluids for infertility, comprising *ebaf*.

32. Please cancel claim 32.

39. (Amended) An isolated and purified peptide comprising CASDGALVPRRLQHRP-amide (SEQ Id No.: 3).

40. (Amended) A detection device for detecting the presence of at least one variant of *ebaf* in an endometrial sample, endometrial fluid, endometrial serum, urine, or saliva.

ABSTRACT

Methods and reagents for the diagnosis of female infertility, prognostic indicators for female infertility, compounds for the treatment of female infertility, compounds and methods for contraception. Methods and compounds are based on the levels of ebaf in endometrial tissue. Methods for diagnosing endometrial receptivity and bleeding function by screening a biological sample such as an endometrial tissue sample, or bodily fluid for the presence of ebaf. A contraceptive compound containing an effective amount of ebaf and a pharmaceutically acceptable carrier. A diagnostic kit for timing contraception containing reagents for screening a sample for the presence of ebaf. A method of treating endometrial irregularities by down-regulating the expression of ebaf.